

**510(k) Summary**

MAR 27 2009

**Date of Summary Preparation:** February 25, 2009

**Submitter:** Virtual Radiologic Corporation  
11995 Singletree Lane  
Suite 500  
Eden Prairie, MN 55344-5349

**Company Contact:** Kimberly Tokach  
Regulatory Compliance Manager

**Manufacturer:** Virtual Radiologic Corporation  
11995 Singletree Lane  
Suite 500  
Eden Prairie, MN 55344-5349

**Device Name:** vRad™ Picture Archiving and Communications System, (PACS)

**Common/Usual Name:** Medical Image Processing Software

**Classification Name:** Picture Archiving and Communications System

**Product Code:** LLZ

**Regulation Number:** 21 CFR 892.2050

**Device Classification:** Class II

**Predicate Devices:** FujiFilm Medical Systems, Synapse Workstation Software, K051553

Fujifilm Medical Systems, Synapse Image Visualization Software (MIP/MPR) Obliquus, K061672

**Device Description:**

vRad™ PACS is a device which consists solely of software and allows electronic transmission of radiological patient images from one location to another. The device has the capability to accept, transfer, display, store, and digitally process medical images to trained and qualified radiologists for the purposes of providing digital diagnostic imaging interpretation services. The software provides functions for performing operations related to image manipulation, enhancement, compression, and quantification of medical images (except mammography images). The software enables the user to display 3D

maximum intensity projection (MIP) and Multi-Planar Reformatting (MPR) visualization of study images.

**Intended Use:**

The vRad™ PACS software is used with general purpose computing hardware, which meets or exceeds minimum specifications. vRad™ PACS software is intended to receive, transmit, store and display images for clinical purposes. The vRad™ PACS Viewer component is intended for installation on an off-the-shelf PC, meeting or exceeding minimum specifications and networked with vRad™ PACS Storage component. The vRad™ PACS Viewer is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The vRad™ PACS Viewer can process medical images from DICOM modalities such as X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from other DICOM compliant modalities.

The vRad™ PACS system should not be used for Mammography primary image diagnosis.

**Comparison of Technological Characteristics:**

The vRad™ PACS shares the same technological characteristics as the predicate devices. These characteristics include similar design, technical requirements and intended use.

**Substantial Equivalence:**

The vRad™ PACS is substantially equivalent to the predicate devices in design, technical requirements and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Virtual Radiologic Corporation  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

**MAR 27 2009**

Re: K090649

Trade/Device Name: vRad™ Picture Archiving and Communications System (PACS) Software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: March 10, 2009  
Received: March 11, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

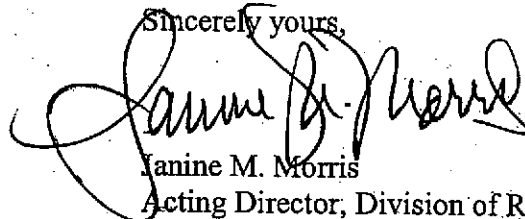
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.suppot/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

Current 510(k) Number: K090649

**Device Name:**

vRad™ Picture Archiving and Communications System (PACS) Software

**Indications for Use:**

The vRad™ PACS software is used with general purpose computing hardware, which meets or exceeds minimum specifications. vRad™ PACS software is intended to receive, transmit, store and display images for clinical purposes. The vRad™ PACS Viewer component is intended for installation on an off-the-shelf PC, meeting or exceeding minimum specifications and networked with vRad™ PACS Storage component. The vRad™ PACS Viewer is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The vRad™ PACS Viewer can process medical images from DICOM modalities such as X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from other DICOM compliant modalities.

The vRad™ PACS system should not be used for Mammography primary image diagnosis.

Prescription Use ☒             
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number K090649